UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,224	09/27/2006	Martin Hendrix	01-2116	3652
<sup>28519</sup> MICHAEL P. N	7590 01/22/201 MORRIS	EXAMINER		
BOEHRINGER INGELHEIM USA CORPORATION			MOORE, SUSANNA	
P O BOX 368	900 RIDGEBURY RD P O BOX 368		ART UNIT	PAPER NUMBER
RIDGEFIELD, CT 06877-0368			1624	
			NOTIFICATION DATE	DELIVERY MODE
			01/22/2010	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

	Application No.	Applicant(s)					
	10/556,224	HENDRIX ET AL.					
Office Action Summary	Examiner	Art Unit					
	SUSANNA MOORE	1624					
The MAILING DATE of this communication ap	pears on the cover sheet with the c	correspondence address					
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
1)⊠ Responsive to communication(s) filed on <u>05 N</u>	lovember 2009						
• • • • • • • • • • • • • • • • • • • •	s action is non-final.						
closed in accordance with the practice under <i>l</i>	,						
Disposition of Claims							
4)⊠ Claim(s) <u>1-7,9 and 13-17</u> is/are pending in the application.							
4a) Of the above claim(s) <u>7 and 13-16</u> is/are withdrawn from consideration.							
5)⊠ Claim(s) <u>1 and 2</u> is/are allowed.							
6)⊠ Claim(s) <u>3-6,9 and 17</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/o	or election requirement.						
Application Papers							
··· <u> </u>	ar						
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correct	• • • • • • • • • • • • • • • • • • • •	, ,					
11) The oath or declaration is objected to by the Ex		•					
Priority under 35 U.S.C. § 119							
12)⊠ Acknowledgment is made of a claim for foreigr	priority under 35 U.S.C. § 119/a	)-(d) or (f)					
a) ⊠ All b) ☐ Some * c) ☐ None of:							
1.☐ Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3.⊠ Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summary						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal F						
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/5/2009.	6) Other:	αιστι / φριισαιιστι					

Application/Control Number: 10/556,224 Page 2

Art Unit: 1624

#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/5/2009 has been entered.

# Response to Amendment

Applicant's arguments, see Remarks, filed 11/5/2009, with respect to Office Action mailed 6/11/2009 have been fully considered. In summary, claims 1-7, 9 and 13-17 are currently pending. Claims 1-6, 9 and 17 are currently under consideration. Claims 7 and 13-16 are currently withdrawn due to nonelected subject matter and election by original presentation. Claims 15-17 are new claims. Based on the restriction requirement claim 17 is under consideration since it is a composition claim.

#### Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/5/2009 was filed after the mailing date of the Non-final Office Action on 10/20/2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

# Specification

The objection of the disclosure is **withdrawn** based on the remarks.

Application/Control Number: 10/556,224 Page 3

Art Unit: 1624

# Claim Rejections - 35 USC § 112

The rejection of claims 1-6 and 9 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutically acceptable salts of a compound of formula (I) does not reasonably provide enablement for a solvate of compound of formula (I) of claim 1 is **withdrawn** based on the amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6, 9 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-6 recites the limitation "pyridyl N-oxide" in the definition of R<sup>2</sup>. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 is indefinite due to the language used in the claim. The preamble states "A pharmaceutical composition comprising a compound according to claim 1..." but claim 17 does not include a carrier, diluent or excipient. If Applicant intends a composition, as the preamble currently reads, please include a carrier, diluent or excipient. If claim 17 is intended as a compound claim, please change the preamble to state so. Therefore, the claim is indefinite since it is uncertain what Applicant is attempting to claim.

## Claim Rejections - 35 USC § 103

The rejection of claims 1-4 and 9 under 35 U.S.C. 103(a) as being unpatentable over Cheng et. al. (J. Org. Chem, 1958, (23) 191-200) is **withdrawn** based on the amendments.

Application/Control Number: 10/556,224 Page 4

Art Unit: 1624

Allowable Subject Matter

Claim 1 and 2 are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/ Examiner, Art Unit 1624